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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Beatrice Mills, Plaintiff, vs. Bristol-Myers Squibb Co.; Sanofi-Aventis U.S. LLC; Sanofi-Aventis U.S. Inc.; Sanofi-Synthelabo Inc., Defendants.	CV 11-00968-PHX-FJM **ORDER**

The court has before it plaintiff's motion for leave to file an amended complaint (doc. 30) and defendants' response (doc. 34). Plaintiff did not reply.

In January 2009, plaintiff was prescribed Clopidogrel (branded as "Plavix") by Dr. Xavier for the treatment of peripheral vascular disease. Plavix is an antiplatelet agent that is designed to prevent blood clots from forming. Between January 7 and January 12, 2009, each day plaintiff ingested one tablet of Plavix along with aspirin pursuant to Dr. Xavier's instructions. On January 12, 2009, plaintiff began bleeding extensively from her rectum. She was brought by ambulance to Mercy Gilbert Medical Center that day. Her bleeding continued, and on January 13, 2009 plaintiff underwent surgery to stop the bleeding. Plaintiff was discharged on January 20, 2009. On January 25, 2009, plaintiff returned to the hospital due to respiratory distress. She was treated for bilateral pulmonary embolism and thrombocytopenia, and was released on January 30, 2009. Plaintiff initiated this action in

the Superior Court of Arizona in Maricopa County and filed a first amended complaint (the "FAC") on January 19, 2011. Defendants timely removed the action on May 16, 2011. This court granted defendants' motion to dismiss all counts without prejudice on August 12, 2011 (doc. 25).

Plaintiff now moves to file a Second Amended Complaint (the "SAC"). The SAC asserts six counts: (1) strict products liability (failure to warn); (2) strict products liability (pursuant to Restatement Second of Torts § 402(a)); (3) negligence; (4) negligent misrepresentation; (5) breach of express warranty; and (6) breach of implied warranty. Defendants argue that leave to amend should be denied as futile.

Rule 15(a), Fed. R. Civ. P. instructs that leave to amend "shall be freely given when justice so requires." If amendment would be futile, however, we deny leave to amend. AmerisourceBergen Corp. v. Dialysist W., Inc., 465 F.3d 946, 951 (9th Cir. 2006). A proposed amendment is futile if it would be subject to immediate dismissal. Steckman v. Hart Brewing, Inc., 143 F.3d 1293, 1298 (9th Cir. 1998). The appropriate test to apply when assessing a proposed amended complaint is the same used to assess the sufficiency of a pleading under Rule 12(b)(6), Fed. R. Civ. P. Nordyke v. King, 644 F.3d 776, 788 n.12 (9th Cir. 2011). To do so, we assess whether plaintiff's proposed SAC contains "well-pleaded factual allegations" that "plausibly give rise to an entitlement to relief." Ashcroft v. Iqbal, __ U.S. __, __, 129 S.Ct. 1937, 1950 (2009).

Plaintiff's allegation of strict products liability is premised on two theories: failure to warn, and design defect. Plaintiff also premises her negligence claim on these theories. For plaintiff to prevail under both theories she must show that the product left the defendants' hands in a defective condition, the defect rendered the product unreasonably dangerous, and the defect was a proximate cause of plaintiff's injuries. Sw Pet Prods., Inc. v. Koch Indus., Inc., 273 F. Supp. 2d. 1041, 1051 (D. Ariz. 2003) (internal citations omitted).

Plaintiff alleges that the chemical structure of Plavix is defective because it carries a higher risk of adverse events for patients who carry the genetic variant CYP, who are poor

metabolizers of the drug.[1] Plaintiff contends that Plavix is the proximate cause of her injuries because, "[u]pon information and belief," she is a CYP carrier. SAC at 10. Twombly does not prevent a plaintiff from pleading facts on information and belief when the information is either "peculiarly" within a defendant's control or where a belief is based on facts that make an inference of liability plausible. Arista Records, LLC v. Doe 3, 604 F.3d 110, 120 (2d Cir. 2010); see also Strand v. John C. Lincoln Health Network, Inc., CV-10-02112-PHX-NVW, 2011 WL 1253408 at *3 (D. Ariz. Mar. 31, 2011) (applying Arista). This is not a case where the facts are in the sole possession of the defendants. Plaintiff's genetic makeup is a fact solely within her control. Tests are available that can reveal whether plaintiff in fact possesses CYP.[2] See Response, ex. D. Neither does her belief that she carries the CYP variant make an inference plausible. According to plaintiff, approximately thirty percent of Caucasians possess the CYP variant. This means that about seventy percent do not. Plaintiff's claim has not moved from the realm of possible to plausible.

Next, plaintiff alleges that Plavix is defective because, when combined with aspirin, it creates a heightened risk of bleeding complications for patients with peripheral vascular disease. To support this allegation, plaintiff first cites the Chan study. Plaintiff asserts that this study found that patients who had previously had stomach ulcers that had healed had higher incidents of stomach bleeding when they took a combination of Plavix and aspirin. Plaintiff, however, does not allege that she had a previously healed stomach ulcer when she took Plavix, and she alleges she experienced rectal, not stomach, bleeding. Thus, the Chan

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[1] Plavix works less effectively in people with the CYP variant. This genetic variation diminishes Plavix's ability to inhibit platelets. In other words, the drug does not prevent blood clots from forming as well for those with the CYP variation. Higher rates of death from cardiovascular causes, heart attack, and stroke among CYP carriers using Plavix have been observed. Jessica L. Mega, M.D., M.P.H., *et al.*, Cytochrome P-450 Polymorphisms and Response to Clopidogrel, 360 New Eng. J. Med. 354 (2009). We may consider documents referenced in the complaint, like this one, when ruling on a Rule 12(b)(6) motion. See Swartz v. KPMG LLP, 476 F.3d 756, 763 (9th Cir. 2007).

[2] We may consider the Plavix label as it is a matter of public record. See Lee v. City of Los Angeles, 250 F.3d 668, 689 (9th Cir. 2001).

study does not show what may be defective about Plavix. Plaintiff also cites the CHARISMA study and "subsequent studies" to support her claim that there is a heightened risk of bleeding complications when patients with her vascular condition ingest Plavix and aspirin. SAC at 9. Viewing the pleading in the light most favorable to plaintiff, Plavix is allegedly defective when ingested along with aspirin by people who have peripheral vascular disease.

However, simply pleading a defect is not enough. To prevail on a design defect claim, a plaintiff must also show that the defective product is unreasonably dangerous. Sw Pet Prods., 273 F. Supp. 2d at 1051. Although plaintiff's design defect claim is pled pursuant to Restatement (Second) of Torts § 402(a), this no longer appears to be the correct standard for design defect claims in Arizona. Although Arizona has not officially adopted the Restatement (Third) of Torts, it "has demonstrated a willingness to look to [it] as the current statement of the law." Gebhardt v. Mentor Corp., 191 F.R.D. 180, 185 (D. Ariz. 1999). See Sw Pet Prods., 273 F. Supp. 2d at 1052 n.17 (collecting cases applying the Restatement (Third) of Torts in Arizona and noting the state's "longstanding policy to look to the Restatement absent contrary precedent"). Courts in this District apply the Restatement (Third) of Torts' definition of an unreasonably safe prescription drug or medical device to Arizona design defect claims. See Gebhardt, 191 F.R.D. at 185; Harrison v. Howmedica Osteonics Corp., CV-06-0745-PHX-RCB, 2008 WL 906585 at *21-22 (D. Ariz. Mar. 31, 2008). Section 6(c) of the Restatement (Third) of Torts declares that

> A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.

Although plaintiff alleges that no reasonable health-care provider would prescribe Plavix for plaintiff knowing of the risks to "Caucasian patients who carry the genetic variant allele CYP who are poor metabolizers of Plavix, and who are diagnosed with peripheral

vascular disease and concomitantly ingest Aspirin," SAC at 24, nowhere does plaintiff allege that Plavix would not be prescribed for any class of patients. See Restatement (Third) of Torts: Prod. Liab., § 6, cmt. b ("Under Subsection (c) a drug is defectively designed only when it provides no net benefit to any class of patients.").

We note that even under a traditional risk/benefit analysis used to determine whether a product is unreasonably dangerous based on the Restatement (Second) of Torts, plaintiff's pleading does not state a plausible claim. See Dart v. Wiebe Mfg., Inc., 147 Ariz. 242, 245-46, 709 P.2d 876, 879-80 (1985) (listing the risk/benefit factors as 1) usefulness of the product, 2) availability of safer products to "meet the same need," 3) "likelihood of injury", 4) obviousness of danger, 5) public expectation of danger, 6) avoidability of injury through due care, and 7) ability to eliminate danger without "seriously impairing the usefulness" of the product or making it too expensive). Plaintiff offers statements including "Plavix was not more efficacious than aspirin" and the risks of bleeding, colectomy, thrombocytopenia, hypotension, and cardiovascular problems "far outweigh any potential benefit to patients," SAC at 8, the risk of respiratory disorders "is greater" than listed on the label, Id. at 12, the risk of "thromboycentica [sic]" is listed on the label as rare, but this risk is "more frequent," Id. at 13, and "there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk" of plaintiff's injuries and were "economically and technologically feasible." Id. at 31-32. Although detailed factual allegations are not necessary in pleadings, "labels and conclusions" are insufficient. Bell Atlantic Corp v. Twombly, 550 U.S. 544, 555, 127 S.Ct. 1955, 1965 (2007). In sum, plaintiff has failed to plead that Plavix was defectively designed.

For plaintiff to establish proximate cause on her failure to warn claim, she needs to show that had a proper warning been given, the injury would not have happened. See Gosewisch v. Am. Honda Motor Co., Inc., 153 Ariz. 400, 403, 737 P.2d 376, 379 (1987) (superceded by statute on other grounds); see also Gebhardt, 191 F.R.D. at 184-85

(granting summary judgment to defendant on failure to warn claim when plaintiff failed to show that a doctor would not have used a medical device on plaintiff if alternative warnings were given). Here, plaintiff pleads "on information and belief" that Dr. Xavier would not have prescribed Plavix had he known of its true risks for patients like plaintiff. SAC at 24. We noted in our dismissal of the FAC that plaintiff "could have contacted her physician" to determine facts that were not solely in the control of defendants. Order at 2. Plaintiff has not done so. In addition, plaintiff's statements regarding the Plavix label's alleged failure to adequately disclose risks of her injury ignores relevant portions describing the risks of major bleeding.[3] See Sprewell v. Golden State Warriors, 266 F.3d 979, 988 (9th Cir. 2001) (we need not "accept as true allegations that contradict matters properly subject to judicial notice or by exhibit"). Thus, plaintiff has not shown that Plavix was defective due to a failure to warn.

Because plaintiff has not pled a plausible strict liability claim, her negligence claim is insufficient. The breach of implied warranty claim also fails. See Hearn v. R.J. Reynolds Tobacco Co., 279 F. Supp. 2d 1096, 1103 (D. Ariz. 2003) (theories of strict liability and breach of implied warranty merge for product liability claims in Arizona). Similarly, plaintiff's express breach of warranty claim is deficient. As in the FAC, the SAC pleads conclusory assertions that "[d]efendants made representations to Plaintiff about the quality or characteristics of P[lavix] by affirmation of fact, promise and/or description." SAC at 39. We explained in our dismissal of the FAC that plaintiff "must actually identify what representations were made to her and how they became the basis of

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[3] For example, plaintiff complains that language in the precautions section only addresses the risk of major bleeding in patients "with recent TIA or stroke who are at high risk of recurrent ischemic events." SAC at 12 (emphasis deleted). However, directly under that section, the label contains information about the rate of "major gastrointestinal bleeding" for patients taking a combination of Plavix and aspirin. See Response, ex. C at 18. Plaintiff's complaint that the label only warns about bleeding from puncture sites is also contradicted by the label, which warns about "an excess in major bleeding in patients receiving Plavix plus aspirin compared with placebo plus aspirin, primarily gastrointestinal and at puncture sites." Id. at 20 (emphasis added).

the bargain." Order at 4 n.3. Plaintiff has not identified any representations.

Finally, plaintiff's negligent misrepresentation fails to satisfy the heightened pleading requirement of Rule 9(b), Fed. R. Civ. P. Plaintiff alleges that the defendants "negligently misrepresented material facts" about Plavix to plaintiff, who, along with her "healthcare providers," "justifiably relied on [d]efendants' misrepresentations." SAC at 38. Plaintiff fails to identify any specific representations that were made, to which of her healthcare providers these were made, and when they where made. Such general allegations do not satisfy Rule 9(b), Fed. R. Civ. P.'s requirement to plead with particularity.

Because plaintiff's allegations in the SAC would not withstand a Rule 12(b)(6) motion to dismiss, amendment would be futile. **IT IS ORDERED DENYING** plaintiff's motion for leave to amend (doc. 30).

The August 26, 2011 Rule 16 scheduling order (doc. 29) noted that no further motions to amend the complaint would be considered after September 2, 2011. Therefore, **IT IS ORDERED DISMISSING** this case with prejudice. The clerk shall enter judgment.

DATED this 7th day of October, 2011.

Frederick J. Martone

Frederick J. Martone
United States District Judge